

further, so that compliance to a standard, which reflects use of our instruments in an 'industrial environment' is met.

Based on our precautionary measures and position in the production, development and manufacturing process, we have never experienced any such problems in our internal testing series, nor from users in the market.

For this reason, we are interested in conducting a thorough inspection of the device in question. The exact reasons for the deviating measurements must be ascertained to either validate your interference theory or identify other causes. Generally, it is very important that instructions and warnings as they are laid out in the respective manuals are taken seriously, as they may affect measurements of blood glucose values. This also highlights the importance of appropriate education of patients performing blood glucose self testing. In this case, for instance, it was extremely important that the patient knew how to compare the meter value against the colour coding. We think that it is extremely useful that you are intending to help remind patients with diabetes that one such instruction and warning relates to the possibility of radio wave interference, which generally may affect any type of portable electronic

device, including portable blood glucose meters.

I. Parfremment

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Do Radio Emissions Cause Accutrend to Malfunction?

Requirements as to interference immunity—EMI for electronic instruments—have been defined in the European Community since 1994. The compliance with these EMI requirements is documented by the CE-mark. The Accutrend and comparable instruments have a immunity value of 3V/m, which is a requirement defined in the European standard 'EN 50082-1'. The compliance of the Accutrend to that requirement has been validated at Boehringer Mannheim by documented test series. To meet Boehringer Mannheim's heavy demands on quality the Accutrend is designed to meet even the considerably higher immunity requirements of the 'EN 50082-2' standard, which is to be used in an 'industrial' environment.

Even with 10V/m of field strength no malfunction or wrong measurement readings occur. This was proved several

times by test series. In further tests it was shown that the Accutrend even works under far more extreme environmental EMI conditions close to conditions by short-wave-transmitters.¹ To sum up, we have not observed influences to the measurement values of the Accutrend caused by radio emissions in the cases noted above (assuming the Accutrend is in good working condition).

To take the exceptional responsibility towards our customers into account, Boehringer Mannheim points out a tolerable remaining risk in the instructions for use, because theoretically there might be higher field strength, especially when safety distances are not kept. The general restriction to the use of laptops in airplanes is comparable to this kind of situation. This similar situation makes it clear why the instructions for use point out the remaining risks.

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Reference

1. *Elektromagnetische Vertraglichkeit*. Ernst Habinger. 33.